JUN 0 4 2014

Section 5 510(k) Summary

510K Submitter Address and Establishment Registration Number:

Registration Number: 1319447
Name: INTERSURGICAL INCORPORATED
Address: 417 Electronics Parkway
Liverpool, NY 13088
Date: May 2, 2014
Contact Person: Michael Zalewski – VP RA/QA/CS
Phone Number: 315-451-2900 X 202
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Classification: 21 CFR 868.5870, Classification Name: Non-rebreathing Valve, Classification Product Code: 73 CBP, Device Class: II, 510K Submission: Traditional.

Predicate Device:

The 1923500 & 1924501 MK3 exhalation valve and the 1924504 MK3b exhalation valves are substantially equivalent to the Intersurgical 1922500 exhalation valve (K984481). The predicate device can be used on a single limb breathing systems. The valve sits on a T-piece connected at the patient end of the breathing tube. When the patient inspires, pressure applied via the exhalation line inflates the valve membrane causing it to close off the exhalation port. Then when the patient exhales the pressure on the membrane is released allowing the exhaled air to escape. The predicate valve has a 1:2 pressure ratio similar to the MKIIIb. The device is for single patient use on adults and pediatrics.

The function of all three valves is the same, however the MK3 and MK3b can seal with a low inspiratory drive in order that the ventilator can trigger a spontaneous breath. IPPB machines in the past had no requirement for PEEP control, however ventilators are generally now fitted with controllable PEEP modes

The predicate device is aesthetically different to the MK3 and MK3b, the MK3 valves are now inline, reducing the need for additional connectors.

Description of Device:

Double limb breathing systems comprising of an inspiratory and expiratory limb is commonly used for respiratory care. To reduce waste and clutter single limb breathing systems can be used with an exhalation valve to dispel exhaled air from the patient. Some ventilator designs or specifications do not require proximal pressure monitoring; airway pressure is monitored inside the ventilator. There are three variants of the exhalation valve in this submission.

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Description of Device:

Exhalation valve with proximal pressure port (1924501 &1924504)
A single breathing tube connects the patient to the ventilator allowing the patient to receive respiratory care. The exhalation valve is connected at the patient end onto the breathing tube. A pressure monitor line and exhalation valve control line directly connects the valve to the ventilator. Via exhalation valve control line, the ventilator applies a pressure which controls the balloon valve. During the Inspiratory phase the balloon is inflated to close off the exhalation port in the valve body. During the expiratory phase the pressure is released in the valve chamber and the balloon deflates allowing air to be expelled to the surrounding environment via the exhalation port. This prevents the patient rebreathing exhaled gases yet allowing for a single limb breathing system to be used instead of a double limb system. The pressure line monitors the pressure in the valve body. The patient end of the exhalation valve has a swivel connector end.

Exhalation valve without proximal pressure port (1923500)
A single breathing tube connects the patient to the ventilator allowing the patient to receive respiratory care. The exhalation valve is connected at the patient end onto the breathing tube. An exhalation valve control line directly connects the valve to the ventilator. Via the exhalation valve control line, the ventilator applies a pressure which controls the balloon valve. During the Inspiratory phase the balloon is inflated to close off the exhalation port in the valve body. During the expiratory phase the pressure is released in the valve chamber and the balloon deflates allowing air to be expelled to the surrounding environment via the exhalation port. This prevents the patient rebreathing exhaled gases yet allowing for a single limb breathing system to be used instead of a double limb system. The patient end of the exhalation valve has a swivel connector end.

Different ventilators require valves which work with different pressure ratios. The MKIII exhalation valve (1923500 and 1924501) has a 1:1.5 pressure ratio which caters for the majority of ventilators. However, there are markets which have applications for ratio of 1:1, and 1:2. The MK3b exhalation valve (1924504) has a 1:2 pressure ratio. The pressure ratio is the pressure difference between the control line pressure and the pressure that will be generated on the patient side of the valve.

Indications for Use:

The exhalation valves are used to control Inspiratory pressure and expel the expired air from a patient being ventilated via a single limb breathing system. The exhalation valve and single limb breathing systems are used with adults/pediatrics and prescribed by a physician. The device can be used within hospitals and for home care use. It is a single patient use device and can be used for a maximum of 30 days.

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Technology Characteristics Summary

The intended use of the Intersurgical Exhalation Valves is comparable to the referenced predicate device. The comparison of the data shows similar values for the key performance characteristics. Proposed devices show similar values for resistance to flow, pressure ratio and leakage when compared to the legally marketed devices.

Non-clinical test results are submitted to confirm product safety and substantial equivalence to predicate device.

Device Comparison Table

Characteristic Compared	MK3 Exhalation Valve – 1923500 non-ported and 1924501 ported	MK3b Exhalation Valve – 1924504 ported	Predicate Exhalation Valve 1922500 K984481
Intended Use:			
Target population	Adult/pediatric patient using a single limb breathing tube.	Adult/pediatric patient using a single limb breathing tube.	Adult/pediatric patient using a single limb breathing tube.
Indications for use Product has been designed and validated for 30 days whereas predicate product was not. It is an improvement on the product, the performance remains comparable to the predicate.	The exhalation valves are used to control Inspiratory pressure and expel the expired air from a patient being ventilated via a single limb breathing system. The exhalation valve and single limb breathing systems are used with adults/pediatrics and prescribed by a physician. The device can be used within hospitals and for home care use. It is a single patient use device and can be used for a maximum of 30 days.	The exhalation valves are used to control Inspiratory pressure and expel the expired air from a patient being ventilated via a single limb breathing system. The exhalation valve and single limb breathing systems are used with adults/pediatrics and prescribed by a physician. The device can be used within hospitals and for home care use. It is a single patient use device and can be used for a maximum of 30 days.	A one-way valve that prevents the escape of inspiratory gases and rebreathing of of expired gases while providing a means of egress for expired gases. Fits all 22 male T-pieces and allows for the use of PEEP valve as the gases exit the valve via a 22mm port. Recommended change: every 24 hours or more frequently if visible deterioration is observed. Single patient use.

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Device Comparison Table

Characteristic Compared	MK3 Exhalation Valve – 1923500 non-ported and 1924501 ported	MK3b Exhalation Valve – 1924504 ported	Predicate Exhalation Valve 1922500 K984481
Where used	Hospital and home	Hospital and home	Hospital and home
Product Labeling	Breathing circuit with exhalation valve.	Breathing circuit with exhalation valve.	Breathing circuit with exhalation valve.
Single Use or Reusable?	Single Patient Use	Single Patient Use	Single Patient Use
Design and Performance:			
Resistance to Flow at 10L/min in mbar	0.6	0.6 same body as MK3	0.6
Resistance to Flow at 30L/min in mbar	0.9	0.9 same body as MK3	1.0
Pressure Ratio	1:1.5	1:2	1:2
Leakage in balloon ml/min	<0.5	0.0	<0.5
Leakage in main body ml/min	<0.5	1.3	3.5
Conditioned/storage testing (-20 degrees + 50 degrees)	Same as mk3b	Complete and pass	Complete and pass
Tapers	Pass	Pass	Pass
Aging 5 year	Pass	Pass	No test work conducted
30 day testing	Pass	Same as MK3	Pass
Trigger	Trigger by 30ms	Same as MK3	N/a different design
Internal Diameter of seat mm	17.17 +/- 0.05	15.5 +/- 0.04	N/a different design
Materials:			
Body	HDPE	HDPE	Styrene Butadiene
Cap	Polypropylene	Polypropylene	Polypropylene
Chamber	Polycarbonate	Polycarbonate	N/A
Valve	Silicone	Silicone	Silicone
Swivel Color	Trans (Clear) Styrene Butadiene	Green Styrene Butadiene	N/A
Energy Used/Delivered:	Air flow through device used to deliver inspiratory air and exhale expiratory air to/from patient	Air flow through device used to deliver inspiratory air and exhale expiratory air to/from patient	Air flow through device used to deliver inspiratory air and exhale expiratory air to/from patient
Compatibility:	Designed for use with single limb breathing tube	Designed for use with single limb breathing tube	Designed for use with single limb breathing tube
Biocompatibility:	ISO 10993	ISO 10993	
Sterility:	Non Sterile	Non Sterile	Non Sterile
Applicable Standards:			
Standards Met:	ISO 5356 (Connectors)	ISO 5356 (Connectors)	ISO 5356 (Connectors)

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Summary of Testing:

Both subject and predicate devices are for use in the hospital and home and are single patient use.
The target population is adult and pediatric patients using a single limb breathing tube. A pediatric population is defined as 10 kg to 40 kg in weight. The product is not for use in neonates.
The resistance to flow through the valve is the same for both predicate and the subject valve.
The pressure ratio for the MK3b and predicate device are exactly the same, meaning it will provide the same performance on the ventilators.
The subject and predicate valve have the same principal of operation.
Although there are a few performance differences between the subject and the predicate devices the intended use is the same. They are used in the same configuration i.e. on a breathing system, connected to a ventilator, except the subject devices incorporate the connector into the design making it more economical, and saves on deadspace.
The leakage in the balloon and the main body is slightly higher in the predicate device than the subject devices, however this leakage is minimal. Intersurgical's internal requirement is for devices to leak less than 5ml/min, however most standard requirements are much larger than this. There is no standard requirement for exhalation valves. The less leakage the more efficient the device will be.
The trigger feature is an additional function which the predicate device is unable to perform, this is a benefit with the new valves and does not alter the intended use, it just means the subject valves can be used on more ventilators. The new valves are validated for patient trigged spontaneous breaths.
The predicate device was previously validated for 24 hours whereas the subject device have been shown to work without any impairment to the performance for 30 days. The predicate device has not been tested for this duration.
Nonclinical tests submitted to demonstrate substantial equivalence for the Exhalation Valve include Resistance to Flow, Pressure Ratio, Leakage and Tapers when compared to the legally marketed device. All materials used in the Exhalation Valve have been evaluated according to tests outlined in ISO 10993-1 and meet the requirements of Bluebook Memo, General Program Memorandum G95-1 biocompatibility testing for genetotoxicity, implantation, cytotoxicity, sensitization, and irritation. The Exhalation Valve connectors meet the requirements of Anesthetic and respiratory equipment – conical connectors: Part 1: Cones and Sockets ISO 5356-1:2004.

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Substantial Equivalence:
Intersurgical Incorporated has demonstrated that the proposed device is as safe and as effective as the predicate device. It is considered to be substantially equivalent to the currently marketed predicate device which has been previously reviewed for market clearance by the FDA.

K132143
Premarket Notification [510(k)] Number

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 4, 2014

Intersurgical, Inc.
Michael Zalewski
Vice President, RA/QA/CS
417 Electronics Parkway
Liverpool, NY 13088-6098

Re: K132143
Trade/Device Name: Exhalation valve
Regulation Number: 21 CFR 868.5870
Regulation Name: Non-rebreathing Valve
Regulatory Class: II
Product Code: CBP
Dated: May 05, 2014
Received: May 06, 2014

Dear Mr. Zalewski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
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Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132143

Device Name

Indications for Use *(Describe)*
Product # 1923500 – MK3 Exhalation Valve without a proximal pressure port
Product # 1924501 – MK3 Exhalation Valve with a proximal pressure port
Product # 1924504 – MK3b Exhalation Valve with a proximal pressure port

Indications For Use: The exhalation valves are used to control Inspiratory pressure and expel the expired air from a patient being ventilated via a single limb breathing system. The exhalation valve and single limb breathing systems are used with adults/pediatrics and prescribed by a physician. A pediatric population is defined as 10 kg to 40 kg in weight. The product is not for use in neonates. The device can be used within hospitals and for home care use. It is a single patient use device and can be used for a maximum of 30 days.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anya C. Harry -S
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